11-16-06

Autorney Docket No.: 6809.220-US

FATENT 3743

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Igor Gonda et al.

Confirmation No.: 8982

Application No.: 09/848,774

Group Art Unit: 3743

Filed: May 3, 2001

Examiner: Lewis, Aaron J.

For: A Method Of Treating Diabetes Mellitus In A Patient

## **CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)**

Date of Deposit: November 14, 2006

Express Mail Label No.: EV 450790041 US

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

I hereby certify that the attached correspondence comprising:

- 1. Information Disclosure Statement
- 2. Form PTO-1449
- 3. Copy of References

is being sent to the United States Patent Office by express mail label no. EV 450790041 US to :

MS: IDS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

on November 15, 2006

Rashida Haji

(name of person mailing paper)

(signature of person mailing paper)

NOV 3 5 2006 gg

**PATENT** 

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Igor Gonda et al. Confirmation No.: 8982

Application No.: 09/848,774 Group Art Unit: 3743

Filed: May 3, 2001 Examiner: Lewis, Aaron J.

For: A Method Of Treating Diabetes Mellitus In A Patient

### INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith references which they believe may be material to the patentability of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

Applicants' attorney wishes to make the Examiner aware of the following co-pending applications which may be related to the instant application: 09/848774, 10/768371, 11/130986, 11/284579, 11/345061, and PCTUS94/01000. Applicants' attorney also notes that application. Serial No. 09/848774 was appealed to the board of appeals and that a decision was rendered on September 7, 2006 affirming the Examiner's rejection of the pending claims and that that decision is the basis of a civil action pursuant to 35 USC 145, which was filed on November 7, 2006 in the United States District Court for the District of Columbia.

While the references may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that the references are "prior art" unless specifically designated as such.

The filing of this Information Disclosure Statement shall not be construed as a representation that no other material references than those listed exist or that a search has been conducted.

Serial No.: 09/848,774; Filed: May 3, 2001

Inventors: Igor Gonda et al.

Title: A Method Of Treating Diabetes Mellitus In A Patient

The references are listed in Form PTO-1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the International Patent references and article references is also enclosed. US Patent references are available at the United States Patent and Trademark Office.

### The references are as follows:

- 1. US 6,737,045
- 2. US 5,394,866
- 3. US 5,192,548
- 4. US 5,458,135
- US 4,790,305 5.
- US 5,363,842 6.
- 7. US 5,167,506
- 8. US 3,362,405
- 9. US 3,425,600
- US 3,540,927 10.
- 11. US 3,554,768
- US 3,620,776 12.
- 13. US 3,666,496
- 14.
- US 3,674,901
- 15. US 3,921,637 US 3,937,668 16.
- 17. US 3,964,483
- US 3,971,852 18. 19. US 3,991,304
- 20. US 3,991,761
- 21. US 3,994,421
- US 4,036,223 22.
- 23. US 4,069,819
- 24. US 4,098,273
- 25. US 4,109,019
- US 4,153,689 26.
- 27. US 4,206,200
- US 4,211,769 28.
- 29. US 4,249,526
- 30. US 4,253,468
- 31. US 4,294,624
- US 4,294,829 32.
- 33. US 4,338,931
- 34. US 4,423,079
- 35. US 4,446,862
- 36. US 4,452,239
- 37. US 4,484,577
- 38. US 4,503,035
- 39. US 4,533,552

Serial No.: 09/848,774; Filed: May 3, 2001

Inventors: Igor Gonda et al.

- 40. US 4,534,343
- 41. US 4,559,298
- 42. US 4,590,206
- 43. US 4,599,311
- 44. US 4,617,272
- 45. US 4,624,251
- 46. US 4,627,432
- 47. US 4,649,911
- 48. US 4,659,696
- 49. US 4,677,975
- 50. US 4,698,328
- 51. US 4,719,762
- 52. US 4,739,754
- 53. US 4,778,054
- 54. US 4,790,305
- 55. US 4,806,343
- 56. US 4,807,814
- 57. US 4,811,731
- 58. US 4,819,629
- 59. US 4,820,534
- 60. US 4,823,784
- 61. US 4,824,938
- 62. US 4,830,858
- 63. US 4,833,125
- 64. US 4,855,157 65. US 4,857,319
- 66. US 4,876,241
- 67. US 4,884,565
- 68. US 4,889,114
- 69. US 4,891,319
- 70. US 4,895,719
- 71. US 4,897,353
- 72. US 4,907,583
- 73. US 4,919,962
- 74. US 4,926,852
- 75. US 4,927,763
- 76. US 4,931,361
- 77. US 4,942,544
- 78. US 4,946,828
- 79. US 4,956,295
- 80. US 4,968,607
- 81. US 4,984,158
- 82. US 4,995,385
- 83. US 5,011,678
- 84. US 5,017,372
- 85. US 5,026,566
- 86. US 5,027,806

Serial No.: 09/848,774; Filed: May 3, 2001

Inventors: Igor Gonda et al.

- 87. US 5,033,463
- 88. US 5,035,237
- 89. US 5,042,975
- 90. US 5,048,514
- 91. US 5,049,388
- 92. US 5,081,228
- 93. US 5,093,316
- 94. US 5,098,893
- 95. US 5,099,833
- 96. US 5,113,855
- 97. US 5,124,162
- 98. US 5,139,016
- 99. US 5,149,543
- 100. US 5,149,653
- 101. US 5,161,524
- 102. US 5,180,812
- 103. US 5,186,164
- 104. US 5,200,399
- 105. US 5,204,108
- 106. US 5,206,200
- 107. US 5,230,884
- 108. US 5,253,468
- 109. US 5,254,330
- 110. US 5,260,306
- 111. US 5,290,765
- 112. US 5,295,479
- 113. US 5,302,581
- 114. US 5,309,900
- 115. US 5,320,094
- 116. US 5,320,714 117. US 5,331,953
- 118. US 5,354,562
- 119. US 5,354,934
- 120. US 5,356,635
- 121. US 5,364,838
- 122. US 5,376,359
- 123. US 5,376,386
- 124. US 5,384,133
- 125. US 5,419,315
- 126. US 5,447,151
- 127. US 5,458,135
- 128. US 5,482,927 129. US 5,506,203
- 130. US 5,518,998
- 131. US 5,558,085
- 132. US 5,619,984
- 133. US 5,672,581

Serial No.: 09/848,774; Filed: May 3, 2001

Inventors: Igor Gonda et al.

- 134. US 5,755,221
- 135. US 5,997,848
- 136. US 6,012,454
- 137. US 6,019,968
- 138. US 6,051,256
- 139. US 6,099,517
- 140. US 6,402,733
- 141. US Patent Application 08/011,281
- 142. WO 90/07351
- 143. WO 93/12823
- 144. WO 93/00951
- 145. WO 92/07599
- 146. Declaration of Reid M. Rubsamen, MD., January 26, 1994
- 147. Declaration of Reid M. Rubsamen, MD., June 6, 1994
- 148. Newman, S.P., Deposition and Effects of Inhalation Aerosols, Dissertation (1983)
- 149. Laube, B.L. et al., JAMA, Vol. 269 (16), pp. 2106-9 (1993)
- 150. Newman, S.P. et al., Respir Dis., Vol. 62, pp. 3-21 (1981)
- 151. Moses, A.C. et al., Diabetes, Vol. 32, pp. 1040-47 (1983)
- 152. Newman, S.P. et al., Thorax, Vol. 36, pp. 52-5 (1981)
- 153. Köhler, Dieter, Lung, (Suppl.), pp. 677-84 (1990)
- 154. Laube, B.L. et al., J Aerosol Med, Vol. 4 (3), pg. 286 (1991)
- 155. Colthorpe, P. et al., Pharma Research, Vol. 9 (6), pp. 764-8 (1992)
- 156. Elliot, R.B. et al., Aust Paediatr J., Vol. 23, pp. 293-7 (1987)
- 157. Wigley, F.M. et al., Diabetes, No. 8, pp. 552-6 (1971)
- 158. Yoshida, H. et al., J Pharma Sci, Vol. 68 (5), pp.670-1 (1979)
- 159. Salzman, R. et al., New Eng J of Med., Vol. 312 (17), pp. 1078-84 (1985)
- 160. Newman, S.P. et al., Am Rev Respir Dis., Vol. 124, pp. 317-20 (1981)
- 161. US 7.028,686
- 162. US 7,021,309
- 163. US 6,647,987
- 164. US 6,688,304
- 165. US 5,743,250
- 166. US 5,522,385
- 167. US 5,509,404
- 168. US 5,394,866
- 169. US 5,941,240
- 170. US 5,934,272
- 171. US 5,915,378
- 172. US 5,888,477
- 173. US 5,884,620
- 174. US 5,873,358
- 175. US 6,431,167
- 176. US 6,431,166
- 177. US 6,427,681
- 178. US 6,408,854 179. US 6,263,872
- 180. US 6,250,298

Serial No.: 09/848,774; Filed: May 3, 2001

Inventors: Igor Gonda et al.

- 181. US 6,192,882
- 182. US 6,167,880
- 183. US 6,131,567
- 184. US 6,123,068
- 185. US 6,098,615
- 186. US 6,085,753
- 187. US 6,024,090
- 188. US 6,012,450
- 189. US 5,970,973
- 190. Moses, A.C. et al., Diabetes, Vol. 32, pp. 1040-7 (1983)
- 191. Hubbard, R.C. et al., Proc. Natl Acad Sci USA, Vol. 86, pp. 680-4 (1989)
- 192. Laube, B.L. et al., J Aerosol Med, Vol. 11 (3), pp. 153-73 (1998)
- 193. Laube, B.L., et al., J Aerosol Med, Vol. 9 (Sppl. 1), pp. S-77-S-91 (1996)
- 194. White, S. et al., Diabetes Tech & Therap., Vol. 7 (6), pp. 896-906 (2005)
- 195. Skyler, J.S. et al., The Lancet, Vol. 357 (9253), pp. 331-5 (2001)
- 196. Laube, B.L. et al., Chest, Vol. 120 (3), pp. 99S-106S (2001)
- 197. Brain, J.D., Diabetes, Obesity and Metab., Vol. 7 (Sppl. 1), pp. S14-S18 (2005)
- 198. Himmelmann, A. et al., DiabetesCare, Vol. 26, pp. 677-82 (2003)
- 199. Patton, J.S. et al., Proc Am Thorac Soc., Vol. 1, pp. 338-44 (2004)
- 200. Klonoff, D.C., Diabetes Tech & Therap., Vol. 1 (3), pp. 307-13 (1999)
- 201. Byron, P.R., Proc Am Thorac Soc., Vol. 1, pp. 321-8 (2004)
- 202. Cefalu, W., DiabetesCare, Vol. 27, pp. 239-46 (2004)
- 203. Lombry, C. et al., Am J Physiol Lung Cell Mol Physiol., Vol. 286, pp. L1002-L1008 (2004)
- 204. Patton, J.S., CHEMTECH, Vol. 27 (12), pp. 34-8 (1997)
- 205. Mandal, T.K., Am J Health-Syst Pharm., Vol. 62 (13), pp. 1359-64 (2005)
- 206. Patton, J.S. et al., Aerosol Insulin A Brief Review, pp. 65-74 (1994)
- 207. Brain, J.D. et al., Bronchial Asthma: Mechanisms and Therap. 2<sup>nd</sup> Ed., pp. 594-603 (1985)
- 208. Brain, J.D. et al., Provocative Challenge Procedures, pp. 1-36 (1989)
- 209. Exubera Medication Guide
- 210. Laube, B.L. et al., JAMA, Vol. 269 (16), pp. 2106-9 (1993)
- 211. Patton, J.S., Application for United States Letters Patent Entitled Inhalation Device
- 212. Newman, S.P. et al., Thorax, Vol. 39, pp. 935-41 (1984)
- 213. Spiro, S.G. et al., Thorax, Vol. 39, pp. 432-5 (1984)
- 214. US 3,764,716

Serial No.: 09/848,774; Filed: May 3, 2001

Inventors: Igor Gonda et al.

Title: A Method Of Treating Diabetes Mellitus In A Patient

It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of record therein. The Examiner is also invited to contact the undersigned if there are any questions concerning this paper or the attached references.

This information disclosure statement is being filed **after** the period set forth in 37 C.F.R. 1.97(b), but **before** the mailing date of any of a final action, a notice of allowance, or an action that otherwise closes prosecution.

Accompanying this information disclosure statement is the fee set forth in 37 C.F.R. § 1.17(p) (currently \$180.00). The Examiner is hereby authorized to charge Deposit Account No. 14-1447 in the amount of \$180.00. A duplicate of this charge directive is attached.

Respectfully submitted,

Date: November 15, 2006

Marc A. Began, Reg. No. 48,829

Novo Nordisk Inc.

Customer Number 23650

(609) 987-5800

Use the following customer number for all correspondence regarding this application

23650

PATENT TRADEMARK OFFICE

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE Atty. Docket No. 6809.220-US

Serial No. 09/848,774

NFORMATION DISCLOSURE STATEMENT BY APPLICANT USE Several sheets if necessary)

Applicant Igor Gonda et al.

Group 3743 Filing Date: May 3, 2001

The market	/	U.S. PATENT DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE			
INITIAL	6,737,045	DATE	NAME	CLASS	50203.150				
	5,394,866								
	5,192,548								
	5,458,135			_					
	4,790,305		<u></u>						
	5,363,842								
	5,167,506								
	3,362,405	1/1968		_		-			
	3,425,600	2/1969			<u>,, </u>				
	3,540,927	11/1970		<del>-   -</del>					
	3,554,768	1/1971	<del></del>						
	3,620,776	11/1971		<del></del> -					
	3,666,496	5/1972							
	3,674,901	7/1972							
	3,921,637	11/1975							
	3,937,668	2/1976							
	3,964,483	6/1976							
	3,971,852	7/1976							
	3,991,304	11/1976							
	3,991,761	11/1976							
	3,994,421	11/1976							
	4,036,223	7/1977							
	4,069,819	1/1978							
	4,098,273	7/1978							
	4,109,019	8/1978			· · · · · ·				
	4,153,689	5/1979							
	4,206,200	6/1980							
	4,211,769	7/1980							
	4,249,526	2/1981				<b> </b>			
	4,253,468	3/1981			<u> </u>	<u> </u>			

EXAMINER

FORM PTO-1449 (Rev. 2-32)

# U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

Atty. Docket No. 6809.220-US

Serial No. 09/848,774

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Applicant Igor Gonda et al.

(Use several sheets if necessary)

Filing Date: May 3, 2001 Group 3743

U.S. PATENT DOCUMENTS FILING DATE DOCUMENT **EXAMINER** IF APPROPRIATE NUMBER SUBCLASS DATE NAME CLASS INITIAL 4,294,624 10/1981 4,294,829 10/1981 4,338,931 7/1982 12/1983 4,423,079 4,446,862 5/1984 6/1984 4,452,239 11/1984 4,484,577 4,503,035 3/1985 4,533,552 8/1985 4,534,343 8/1985 4,559,298 12/1985 4,590,206 5/1986 4,599,311 7/1986 4,617,272 10/1986 4,624,251 11/1986 4,627,432 12/1986 3/1987 4,649,911 4,659,696 4/1987 4,677,975 7/1987 10/1987 4,698,328 4,719,762 1/1988 4,739,754 4/1988 4,778,054 10/1988 4,790,305 12/1988 4,806,343 2/1989 2/1989 4,807,814 4,811,731 3/1989 4,819,629 4/1989 4,820,534 4/1989

EXAMINER

4,823,784

DATE CONSIDERED

4/1989

FORM PTO-1449 (Rev. 2-32)

# U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

Atty. Docket No. 6809.220-US

Serial No. 09/848,774

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Applicant Igor Gonda et al.

(Use several sheets if necessary)

Filing Date: May 3, 2001 Group 3743

U.S. PATENT DOCUMENTS FILING DATE **EXAMINER** DOCUMENT IF APPROPRIATE SUBCLASS NUMBER DATE NAME CLASS INITIAL 4,824,938 4/1989 4,830,858 5/1989 4,833,125 5/1989 8/1989 4,855,157 8/1989 4,857,319 10/1989 4,876,241 12/1989 4,884,565 4,889,114 12/1989 4,891,319 1/1990 <u>4,895,</u>719 1/1990 1/1990 4,897,353 3/1990 4,907,583 4,919,962 4/1990 5/1990 4,926,852 4,927,763 5/1990 4,931,361 6/1990 4,942,544 7/1990 4,946,828 8/1990 9/1990 4,956,295 11/1990 4,968,607 4,984,158 1/1991 4,995,385 2/1991 5,011,678 4/1991 5,017,372 5/1991 5,026,566 6/1991 5,027,806 7/1991 5,033,463 7/1991 7/1991 5,035,237 5,042,975 8/1991 9/1991 5,048,514

EXAMINER

FORM PTO-1449 (Rev. 2-32)

EXAMINER

# U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

Atty. Docket No. 6809.220-US

Serial No. 09/848,774

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Applicant Igor Gonda et al.

(Use several sheets if necessary)

Filing Date: May 3, 2001 Group 3743

U.S. PATENT DOCUMENTS								
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE		
	5,049,388	9/1991						
	5,081,228	1/1992						
	5,093,316	3/1992			-			
	5,098,893	3/1992						
	5,099,833	3/1992						
	5,113,855	5/1992						
	5,124,162	6/1992						
	5,139,016	8/1992						
	5,149,543	9/1992						
	5,149,653	9/1992						
	5,161,524	11/1992						
	5,180,812	1/1993						
	5,186,164	2/1993						
	5,200,399	4/1993						
	5,204,108	4/1993						
	5,206,200	4/1993						
	5,230,884	7/1993						
	5,253,468	10/1993						
	5,254,330	10/1993						
	5,260,306	11/1993						
	5,290,765	3/1994						
	5,295,479	3/1994						
	5,302,581	4/1994						
	5,309,900	5/1994						
	5,320,094	6/1994						
	5,320,714	6/1994						
	5,331,953	7/1994						
	5,354,562	10/1994						
	5,354,934	10/1994						
	5,356,635	10/1994						

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**FORM PTO-1449** (Rev. 2-32)

#### U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

Atty. Docket No. 6809.220-US

Serial No. 09/848,774

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Applicant Igor Gonda et al.

(Use several sheets if necessary)

Filing Date: May 3, 2001

**Group 3743** 

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
INITIAL		11/1994	Milita	CLASS	50000.100	
	5,364,838		····			
	5,376,359	12/1994				
	5,376,386	12/1994				
	5,384,133	1/1995			·	
	5,419,315	5/1995				
	5,447,151	9/1995				
	5,458,135	10/1995				
	5,482,927	1/1996				
	5,506,203	4/1996				<u> </u>
	5,518,998	5/1996				
	5,558,085	9/1996				
	5,619,984	4/1997				
	5,672,581	9/1997				
	5,755,221	5/1998				
	5,997,848	12/1999				
	6,012,454	1/2000				
	6,019,968	2/2000				
	6,051,256	4/2000				
	6,099,517	8/2000				
	6,402,733	6/2002				
	7,028,686					ļ
	7,021,309					
	6,647,987		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
	6,688,304		"11			
	5,743,250					
	5,522,385	ļ				
	5,509,404		<u></u>			
	5,394,866					
	5,941,240					
	5,934,272					<u> </u>

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2-32)

EXAMINER

# U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

Atty. Docket No. 6809.220-US

Serial No. 09/848,774

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Applicant Igor Gonda et al.

(Use several sheets if necessary)

Filing Date: May 3, 2001 Group 3743

U.S. PATENT DOCUMENTS FILING DATE EXAMINER DOCUMENT IF APPROPRIATE CLASS **SUBCLASS** NUMBER DATE NAME INITIAL 5,915,378 5,888,477 5,884,620 5,873,358 6,431,167 6,431,166 6,427,681 6,408,854 6,263,872 6,250,298 6,192,882 6,167,880 6,131,567 6,123,068 6,098,615 6,085,753 6,024,090 6,012,450 5,970,973 10/1973 3,764,716

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2-32)

#### U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

Atty. Docket No. 6809.220-US

Serial No. 09/848,774

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Applicant Igor Gonda et al.

(Use several sheets if necessary)		Filing Date: May 3, 200	Group 3743								
		FOREIGN	PATENT DOCUMENTS								
	DOCUMENT					TRANSLATION					
	NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	YES	NO				
	90/07351	01/08/90	WO								
	93/12823	12/18/92	wo								
	93/00951	07/02/92	WO								
	92/07599	10/25/91	WO								
	OTHER D	OCUMENTS (Includ	ing Author, Title, Date, Pertin	ent Pages, Et	c.)		<del></del>				
	<del>                                      </del>	cation 08/011,281									
	<del></del>	Declaration of Reid M. Rubsamen, MD., January 26, 1994									
	Declaration of R	Declaration of Reid M. Rubsamen, MD., June 6, 1994									
	Newman, S.P., I	Newman, S.P., Deposition and Effects of Inhalation Aerosols, Dissertation (1983)									
	Laube, B.L. et a	Laube, B.L. et al., JAMA, Vol. 269 (16), pp. 2106-9 (1993)									
	Newman, S.P. e	Newman, S.P. et al., Respir Dis., Vol. 62, pp. 3-21 (1981)									
	Moses, A.C. et al., Diabetes, Vol. 32, pp. 1040-47 (1983)										
	Newman, S.P. e	Newman, S.P. et al., Thorax, Vol. 36, pp. 52-5 (1981)									
	Köhler, Dieter,	Köhler, Dieter, Lung, (Suppl.), pp. 677-84 (1990)									
	Laube, B.L. et a	Laube, B.L. et al., J Aerosol Med, Vol. 4 (3), pg. 286 (1991)									
	Colthorpe, P. et	Colthorpe, P. et al., Pharma Research, Vol. 9 (6), pp. 764-8 (1992)									
	Elliot, R.B. et al	Elliot, R.B. et al., Aust Paediatr J., Vol. 23, pp. 293-7 (1987)									
	Wigley, F.M. et	Wigley, F.M. et al., Diabetes, No. 8, pp. 552-6 (1971)									
	Yoshida, H. et a	Yoshida, H. et al., J Pharma Sci, Vol. 68 (5), pp.670-1 (1979)									
	Salzman, R. et a	Salzman, R. et al., New Eng J of Med., Vol. 312 (17), pp. 1078-84 (1985)									
	Newman, S.P. e	Newman, S.P. et al., Am Rev Respir Dis., Vol. 124, pp. 317-20 (1981)									
	Moses, A.C. et a	Moses, A.C. et al., Diabetes, Vol. 32, pp. 1040-7 (1983)									
	Hubbard, R.C.	et al., Proc. Natl A	cad Sci USA, Vol. 86, pp.	680-4 (198	9)						
	Laube, B.L. et a	Laube, B.L. et al., J Aerosol Med, Vol. 11 (3), pp. 153-73 (1998)									
	Laube, B.L., et	al., J Aerosol Med	, Vol. 9 (Sppl. 1), pp. S-7	7-S-91 (199	96)						
	White, S. et al.,	Diabetes Tech &	Therap., Vol. 7 (6), pp. 890	5-906 (200	5)						
	Skyler, J.S. et a	l., The Lancet, Vo	l. 357 (9253), pp. 331-5 (2	001)							
EXAMINER			DATE CONSIDERED								

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Rev. 2-32)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		Atty. Docket No. 6809.220-	Serial No. 09/848,774						
, ,	INFORMATION DISCLOSURE STATEMENT BY APPLICANT			Applicant Igor Gonda et al.						
(Use several sheets if necessary)			Filing Date: May 3, 2001 Group 3743							
-		FOREIGN	PATENT DOCUMENTS							
	DOCUMENT				TRANSLATION					
	NUMBER	DAŢE	COUNTRY	CLASS	SUBCLASS	YES	NO			
	OTHER I	OCUMENTS (Includin	g Author, Title, Date, Pertine	ent Pages, Et	c.)		<u> </u>			
	Laube, B.L. et a	il., Chest, Vol. 120 (	3), pp. 99S-106S (2001)							
		Brain, J.D., Diabetes, Obesity and Metab., Vol. 7 (Sppl. 1), pp. S14-S18 (2005)								
	Himmelmann, A	Himmelmann, A. et al., DiabetesCare, Vol. 26, pp. 677-82 (2003)								
		Patton, J.S. et al., Proc Am Thorac Soc., Vol. 1, pp. 338-44 (2004)								
	Klonoff, D.C., I	Klonoff, D.C., Diabetes Tech & Therap., Vol. 1 (3), pp. 307-13 (1999)								
	Byron, P.R., Pro	Byron, P.R., Proc Am Thorac Soc., Vol. 1, pp. 321-8 (2004)								
	Cefalu, W., Dia	Cefalu, W., DiabetesCare, Vol. 27, pp. 239-46 (2004)								
	Lombry, C. et a	Lombry, C. et al., Am J Physiol Lung Cell Mol Physiol., Vol. 286, pp. L1002 L1008 (2004)								
<del></del>	Patton, J.S., CH	Patton, J.S., CHEMTECH, Vol. 27 (12), pp. 34-8 (1997)								
	Mandal, T.K., A	Mandal, T.K., Am J Health-Syst Pharm., Vol. 62 (13), pp. 1359-64 (2005)								
		Patton, J.S. et al., Aerosol Insulin – A Brief Review, pp. 65-74 (1994)								
j		Brain, J.D. et al., Bronchial Asthma: Mechanisms and Therap. 2 <sup>nd</sup> Ed., pp. 594-603 (1985)								
		Brain, J.D. et al., Provocative Challenge Procedures, pp. 1-36 (1989)								
		Exubera Medication Guide								
		Laube, B.L. et al., JAMA, Vol. 269 (16), pp. 2106-9 (1993)								
		Patton, J.S., Application for United States Letters Patent Entitled Inhalation Device								
		Newman, S.P. et al., Thorax, Vol. 39, pp. 935-41 (1984)								
		Spiro, S.G. et al., Thorax, Vol. 39, pp. 432-5 (1984)								
	Spiro, S.O. et al	., x 1101 un, + 01. 57, p			. <u>.</u>					
EXAMINER			DATE CONSIDERED			·	<u></u>			

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.